

RECALL NOTICE – ACTION REQUIRED A&E MEDICAL SURGICAL PUNCH – ALL MODEL NUMBERS, ALL CURRENT INVENTORY All LOTS THRU 0230P

October 20, 2017

Dear Valued Distributor:

All A&E Medical Surgical Punches are being recalled due to potential packaging damage which may have occurred during transportation resulting in a loss of sterility. Recent testing has identified certain shipping configurations which may cause damage to the sterile barrier pouch if the Surgical Punches experience excessive movement from multiple drops during transport. Consequently, in an abundance of caution, A&E is recalling all unused Surgical Punches with current shelf life even though there has been no reported pouch damage from our customers. For a complete listing of the affected inventory shipped to your account, please see the listing included with this letter.

A&E has validated specific transport configurations which will protect the Surgical Punch packaging from damage during transportation ensuring that the product will remain sterile until use. Therefore, we will be able to provide you with replacement inventory.

This affects all sterile surgical punches with lot numbers from 0090P through 0230P. Please contact all customers who have received product from these lots immediately and retrieve all unused product. This product must be returned to A&E. Additionally, for any distributors outside the US, EU, or Canada, please ensure that you provide the appropriate governmental notifications relative to this recall. Please provide copies of any country notifications to A&E Medical for our recall files. If you require additional information in support of these notifications, please contact your company representative or contact the company as indicated on the Acknowledgement Form.

Please complete and return the Acknowledgement Form (page 2) immediately so that A&E can assure all customers are aware of the actions required. Please provide an account of product to be returned as soon as possible but not less than 30 days after receipt of this notice.

We sincerely apologize for the inconvenience of this recall. We are committed to providing the highest quality product for you and your patients.

Thank you very much,

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